Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION
   Product Name: Nisseiken Avian Colibacillosis Vaccine
   Company Name: Nisseiken Co., Ltd.
   Address: 9-2221-1 Shin-machi, Ome, Tokyo 198-0024, Japan
   Tel.: +81-428-33-1001
   Responsible Dept.: Business department
   Tel.: +81-428-33-1003
   Fax.: +81-428-33-1130
   Recommended Use/Restriction of Use: Veterinary medicinal products

2. HAZARDS IDENTIFICATION
   Most Important Hazard: None
   Hazards: None
   Environmental Impact: No data available
   Physical and Chemical Hazards: None
   Specific Hazards: None
   Main Symptoms: None
   Classification Name: None
   Summary of Expected Emergency: None
3. **COMPOSITION/INFORMATION ON INGREDIENTS**

Single Component or Mixture: Mixture
Generic name: Avian *Escherichia coli* live vaccine

Ingredients and Contents: Per 1,000 doses of the vaccine

<table>
<thead>
<tr>
<th>Component Name</th>
<th>Contents</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Avian <em>Escherichia coli</em> serotype O78, AESN1331</td>
<td>$1 \times 10^{10}$-$1 \times 10^{12}$ CFU</td>
<td>Not applicable</td>
</tr>
<tr>
<td>strain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2) Skim milk</td>
<td>100 mg</td>
<td>Not applicable</td>
</tr>
<tr>
<td>(3) Yeast extract</td>
<td>1.3%</td>
<td>8013-01-2</td>
</tr>
<tr>
<td>(4) D-Sorbitol</td>
<td>2.5%</td>
<td>50-70-4</td>
</tr>
</tbody>
</table>

Chemical Properties (chemical formula):
(1) - (3); Not applicable
(4); $C_6H_{14}O_6$

Official Gazette Notification Reference Number (Chemical Substances Control Law):
(1) - (3); Not applicable
(4); 8-50

Components Contributing to the Hazard: Not applicable
Impurities Contributing to the Hazard: Not applicable
4. FIRST AID MEASURES
   In Case of Inhalation: Expose the users to fresh air and, if necessary, seek medical treatment with a description attached to the product.
   In Case of Contact with Skin: Wash out with soap and water as necessary, and disinfect with 70% alcohol.
   In Case of Contact with Eye: Flush with water or warm water and, if necessary, seek medical treatment with a description attached to the product.
   In Case of Ingestion: Wash the mouth well with water and, if necessary, seek medical treatment with a description attached to the product.
   Brief Information Concerning the Most Important Signs and Symptoms: Not applicable
   Protection for Persons who Practice First Aid Measures: Not applicable
   Special Precautions for Doctor: Not applicable

5. FIRE-FIGHTING MEASURES
   Extinguishing Media: Water, sand, carbon dioxide, and dry chemical powder or foam
   Extinguishing Media to Avoid: Not specified
   Specific Hazards Arising from the Product: Not applicable
   Specific Fire-Fighting: Spread extinguishing media to the fire sources.
   Protection for Persons Who Extinguish a Fire: Not specified

6. ACCIDENTAL RELEASE MEASURES
   Personal Precautions: No data available
   Environmental Precautions: No data available
   Methods for Cleaning Up: Collect in a vessel as much as possible, and disinfect with 70% alcohol.
   Prevention of Second Accident: No data available

7. HANDLING AND STORAGE
   Handling:
   Technical Measures: Not applicable
   Precautions:
   (1) Do not use the product with any abnormal appearance and content.
   (2) Do not use the vaccine after expiry.
   (3) Do not add other medicinal products (vaccines) to the product.
   (4) Use sterilized or boiled sprayer or coarse sprayer.
   Do not use ones disinfected with chemical agent (except for gas sterilization) or contaminated by other medicine. When sterilize injection devices by dry heat, steam or boiling, use them after they return to ambient temperature.
   (5) Shake well to homogenize the vaccine before using it.
   (6) Before use, disinfect a rubber cap of the lyophilized vaccine container, insert about 4 mL saline for 1,000 doses into it, and shake well to dissolve uniformly.
   (7) Insert a sterilized needle into the rubber cap, absorb the dissolved vaccine and insert into a bottle of a fine or coarse sprayer. Read an instruction of the fine or coarse sprayer when using them, and follow the precautions.
   (8) Avoid physical damage to the vaccine vial, because it may break due to vacuum.
   (9) Cautions should be taken not to cut your fingers with the cut section of the aluminum cap when opening the vial.

   Safely Handling Precautions:
   Precautions:
   (1) Worker shall use of protective barriers (e.g., eye protection, mask, and gloves) to protect one’s body.
   (2) Wash hands well with soap after handling.
Storage:
Appropriate Storage Conditions:
(1) Store in light-resistant containers below 10 °C.
(2) Keep the product out of children’s reach.
(3) Avoid direct sunlight because it influences the product quality.

Safe Packaging Materials: No data available

8. EXPOSURE CONTROLS/PERSONAL PROTECTION
Appropriate Engineering Controls: No data available
Occupational Exposure Limit: No data available
Administrative Exposure Limit: No data available
Protective Equipment
  Respiratory Protective Equipment: Not applicable
  Hand Protection: Not applicable
  Eye Protection: Not applicable
  Skin and Body Protection: Not applicable
Appropriate Hygiene Measures: No data available

9. PHYSICAL AND CHEMICAL PROPERTIES
Physical State
  Shape: Solid
  Color: Pale yellow-grayish brown to pale yellowish gray colored dried material. When reconstituted with physiological saline and mixed, it turns to pale yellowish gray colored homogeneous opaque liquid.
  Odor: Odorless
  pH: No data available
Physical State Changing Specific Temperature/Temperature Range
  Boiling Point: No data available
  Boiling Range: No data available
  Melting Point: No data available
  Decomposition Temperature: No data available
  Flash Point: No data available
  Ignition Point: No data available
  Explosive Properties: Not applicable

10. STABILITY AND REACTIVITY
Stability: No data available
Reactivity: No data available
Conditions to Avoid: No data available
Materials to Avoid: No data available
Hazardous Decomposition Products: No data available
Others: No data available

11. TOXICOLOGICAL INFORMATION
Acute Toxicity: No data available
Local Effect: No data available
Sensitization: No data available
Chronic/Long-Term toxicity: No data available
Carcinogenicity: No data available
Mutagenicity: No data available
Teratogenicity: No data available
Reproductive Toxicity: No data available
Others: Not applicable

12. ECOLOGICAL INFORMATION
   Mobility: No data available
   Persistence/Degradability: No data available
   Bioaccumulative Potential: No data available
   Biotoxicity: No data available
   Fish Toxicity: No data available
   Others: No data available

13. DISPOSAL CONSIDERATIONS
   Dispose the left over vaccine and used bottles in accordance with laws enacted by a local public entity, or process them as infectious waste after disinfection or sterilization. Flush the used apparatus with water after sterilizing.

14. TRANSPORT INFORMATION
   International Regulations: No data available
   UN Class: No data available
   UN No.: No data available
   Domestic Regulations: No data available
   Additional Regulations: No data available
   Specific Safety Measures and Conditions for Transport: No data available

15. REGULATORY INFORMATION
   The Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices
   Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof: Not applicable

16. Other Information
   (1) This drug is specified as powerful drug in The Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices.
   (2) This product should be used only pursuant to the prescription or direction of a veterinarians, because it is a prescription drug.
   (3) Confirm precautions mentioned in a description attached to the product before use.
   (4) In case of accidental exposure of the vaccine in your eyes, nose, or mouth, flush the exposed parts with water. If necessary, seek medical advice and show the package insert or the label to the physician.

The information above is believed to be accurate and represents the best information currently available to us for safe handling, use, treatment, store, transport, disposal, and accidental release measures of this product. However, it is not to guarantee anything and not to specify the quality.